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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,057	11/21/2000	Michael Brines	10165-010-999	5119

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EXAMINER
DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/717,057	BRINES ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- *The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Status of Application, Amendments and/or Claims

The amendment filed 01 May 2003 (Paper No. 18) has been entered in full. Claims 8, 10 and 11 were cancelled. Claims 1-7, 9 and 10 are under examination.

Priority under 35 U.S.C. 120 for the instant application has been met.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The rejection of claim 1 under 35 U.S.C. 112, second paragraph as set forth at page 7 of the previous Office Action (01 November 2002, Paper No. 16) is *withdrawn* in view of the amendment (01 May 2003, Paper No. 18).

The rejection of claims 1-7, 9 and 10 under 35 U.S.C. 102(b) as being anticipated by Grimm *et al.* (IDS#BC, submitted by Applicant, Paper No. 6) as set forth at page 10 of the previous Office Action (01 November 2002, Paper No. 16) is *withdrawn* in view of the amendment (01 May 2003, Paper No. 18).

The rejection of claims 1-7, 9 and 10 under 35 U.S.C. 102(b) as being anticipated by Marsh *et al.* (IDS#BP, submitted by Applicant, Paper No. 6) as set forth at page 10 of the previous Office Action (01 November 2002, Paper No. 16) is *withdrawn* in view of the amendment (01 May 2003, Paper No. 18).

Claim Rejections - 35 USC § 112, first paragraph, scope of enablement

Claims 1-7 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for enhancing the function of normal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO, does not reasonably provide enablement for a method for enhancing the function of *abnormal excitable tissue* in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or the invention commensurate in scope with these claims. The basis for this rejection is set forth at pages 5-6 of the previous Office Action (01 November 2002, Paper No. 16).

Applicant states that Exhibit D is a compilation of data presented as examples in Applicant's copending applications which utilize the teaching provided in the instant specification to corroborate the method for enhancing learning and memory in mammals with abnormal excitable tissue by peripherally administering EPO. Applicant states that EPO improved the brain function of traumatized mice, as manifested by improved swim times. Applicant states that both forms of EPO (unmodified and asialo) are efficacious at enhancing function in the kainate-treated animals, as shown by increased time to death.

Applicant's arguments have been fully considered but not deemed persuasive because Applicant has not sworn to the truth of the data (Exhibit D). Applicant states

that Exhibit D is a compilation of data presented as examples in Applicant's copending application. The copending applications, however, were never identified by their application number, therefore the oath and declaration in those applications cannot be checked. If properly submitted, the data would be convincing, thus obviating the instant rejection.

Double Patenting

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending **Application No. 09/547,220**. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The basis for this rejection is set forth at pages 7-8 of the previous Office Action (01 November 2002, Paper No. 16).

Claim 1 of the instant application is drawn to a method for enhancing the function of normal or abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO. Claim 1 of application 09/547,220 is drawn to a method for treating cerebral ischemia in a mammal comprising peripherally administering to said mammal a non-toxic amount of erythropoietin effective to exert a neuroprotective effect.

Applicant states that claim 1 is based on the discovery by the Applicants that erythropoietin can cross endothelial cell barriers, and can thus be used to enhance learning and memory in normal and abnormal mammals. Applicant states that claim 1

of the '220 application is based on the ability of erythropoietin to cross the blood-brain barrier. Applicant maintains that without the additional information provided by the disclosure of the instant application that erythropoietin can be used to enhance learning and memory one skill in the art would not understand from reading claim 1 of the '220 application that erythropoietin could be used to enhance the function of excitable tissue. Applicant states that the disclosure of the patent may not be used as prior art.

Applicant's arguments have been fully considered but not deemed persuasive. One skilled in the art without reading the disclosure would not know about Applicant's discovery regarding barriers. One skilled in the art would see one claim drawn to enhancing the function of normal or abnormal excitable tissue in a mammal comprising administering to said mammal a peripherally effective non-toxic, excitable tissue enhancing amount of EPO ('057 application) and the other claim drawn to treating cerebral ischemia in a mammal comprising peripherally administering to said mammal a non-toxic amount of erythropoietin effective to exert a neuroprotective effect. ("220 application). The specification can be used to define a term that is not clear. The specification defines "excitable tissue" as neuronal and cardiac tissue (page 1, lines 13-14). A method for enhancing the function of abnormal excitable (neuronal) tissue would encompass treating cerebral ischemia. The two inventions are obvious. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending **Application No. 09/717,053**. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The basis for this rejection is set forth at pages 8-9 of the previous Office Action (01 November 2002, Paper No. 16).

Claim 1 of the instant application is drawn to a method for enhancing the function of normal or abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO. Claim 1 of application 09/717,053 is drawn to a method for the prevention or treatment of a neuromuscular or muscular condition comprising administering peripherally to said mammal an effective amount of EPO for the protection of a heart disease.

Applicant states that only by deviating from claims and reading the additional disclosure provided by the specification would the skilled artisan know that erythropoietin can cross other endothelial barriers and used to enhance the function of excitable cells.

Applicant's arguments have been fully considered but not deemed persuasive. As was stated above, the specification defines "excitable tissue" as neuronal and cardiac tissue. It would be obvious to one skilled in the art without reading the disclosure that a method for enhancing the function of normal or abnormal excitable

(cardiac) tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO would encompass a method for the prevention or treatment of a neuromuscular or muscular condition comprising administering peripherally to said mammal an effective amount of EPO for the protection of a heart disease. The instant claims overlap as both comprise administering peripherally the same agent and are drawn to treatment of overlapping tissue types. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending **Application No. 09/716,960**. Although the conflicting claims are not identical, they are not patentably distinct from each other. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. The basis for this rejection is set forth at pages 9-10 of the previous Office Action (01 November 2002, Paper No. 16).

Claim 1 of the instant application is drawn to a method for enhancing the function of normal or abnormal excitable tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO. Claim 1 of application 09/716,960 is drawn to a method for preventing or treating a neurodegenerative condition comprising administering peripherally to said mammal an effective amount of erythropoietin.

Applicant states that the skilled artisan would not be able to understand, based on the claimed invention alone, the ability of erythropoietin to prevent or treat neurodegenerative conditions provided by the invention defined by claim 1 of the '960 application, that erythropoietin can cross other endothelial barriers and enhance the function of excitable tissue.

Applicant's arguments have been fully considered but not deemed persuasive. It would be obvious to one skilled in the art without reading the disclosure that a method for enhancing the function of abnormal excitable (neuronal) tissue in a mammal comprising administering peripherally to said mammal a peripherally effective, non-toxic, excitable tissue enhancing amount of EPO would encompass a method for preventing or treating a neurodegenerative condition comprising administering peripherally to said mammal an effective amount of erythropoietin. The instant claims overlap as both comprise administering peripherally the same agent and are drawn to treatment of overlapping tissue types. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (703) 305-6915. The examiner can normally be reached on 9:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

RMD
July 11, 2003

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600